In the Specification:

Listed below are amended paragraphs of the Specification. A clean version of the specification (pages 1-67) is in the attached appendix following page 18 of this paper for the convenience of the Examiner.

On page 28, please delete the paragraph beginning on line 27, and substitute therefor:

The imaging data is often acquired as sectional views (see, for examples FIG. 4, 5). For example, sectional views of a portion of a heart along the long axis are depicted in FIG. 4. Each sectional view (91, 92, 93, and 94) is taken along a different cross section of the portion of the heart. For example, sectional view 91 represents the image of the portion of the heart along plane AA. Other sectional views (92, 93, and 94) are collected along other planes (e.g., BB, CC, DD, EE, FF, or GG). Alternatively, data may be collected along the short axis of the portion of the heart as depicted in FIG. 5. FIG. 5 depicts three cross-sectional views (104, 105, and 106) of the heart 100 along planes XX, YY and ZZ (respectively). In another embodiment, data from both long axis and short axis smays of the heart may be used to prepare the computer model. It should be understood that the data from the long and short axis smays may be redundant and sectional data along only one of the axis may be necessary to create a model.

On page 29, please delete the paragraph beginning on line 9, and substitute therefor:

After the sectional views have been collected, the views may be combined to generate a three-dimensional computer model of the heart. One method of combining

these sectional views and converting them into a model may be done by overlaying the sectional views on a XY grid. FIG. 6 shows the cross-sectional view 91 of the heart along the long axis at plane AA from FIG. 4 with a grid superimposed over the cross-section. The points of intersection of endocardium (P_I, 133), and the epicardium (P_O, 132) with the grid lines are identified in XY coordinates, as depicted in FIG. 6. Similarly, XY coordinates of the other cross-sections (e.g., cross-sections 92, 93, and 94) are also identified using a grid. Since the angular relationship between each plane is known (e.g., angle θ between planes AA and GG as depicted in FIG. 4), all the data points may be converted into XYZ coordinates. The boundary layer generated by connecting the internal points P_I of each cross-section defines the endocardial boundary 131, and the boundary layer generated by connecting the external points P_O of each cross-section defines the epicardial boundary 130. In this manner, the heart may be defined in a three-dimensional space. Once the three-dimensional model is created a time frame of the heart over which all the images were made may be added to show the heart movement during its cardiac cycle. In this manner a "four-dimensional" heart model may be created.

On page 29, please delete the paragraph beginning on line 28, and substitute therefor:

Once the multi dimensional object is defined, it may be converted to elements of a finite element model and a finite element mesh that represent the heart and its components to create model 140 as depicted in FIG. 7. Some of the components of the heart that may be identified as different features of a finite element model are listed below (depicted in FIG. 8) but the apparatus and method is not limited to these components:

On page 31, please delete the paragraph beginning on line 20, and substitute therefor:

In an embodiment, an image may be interactively connected to a model to allow the physician to simulate the effects of the treatment before it is administered. For example, a pull down menu may be accessed to select the type of treatment desired (see FIG. 3, (12)). For example, treatments for the correction of a cardiac valve may be listed. Examples of possible cardiac valve treatments include, but are not limited to inserting a synthetic valve (e.g., a St. Jude mechanical valve or a Baxter tissue valve), insertion of an annuloplasty ring, and/or performing a surgical repair (e.g., moving papillary muscle locations, surgical ventricular repair, bypass grafting, mitral valve repair, etc.). For example, a physician may select the mitral valve option to shorten the chordae tendinae or tighten the mitral annulus. In the chordae tendinae example, the model may separate the chordae elements from the entire model and present it to the physician, to allow the physician to interact with the elements. Once the physician has shortened the chordae the model presents the image of the new shorter element and presents an image of the other elements with the effect that the shortening of the chordae has had on them along with clinical outcomes (16)(17).

On page 35, please delete the paragraph beginning on line 23, and substitute therefor:

FIG. 11 depicts a Frank-Starling curve of a ventricle. The heart has the intrinsic capability of increasing its force of contraction when preload is increased. Preload may be defined as the initial stretching of the cardiac myocytes prior to contraction and is related to the sarcomere length. When venous return is increased to the heart, ventricular filling and hence preload (depicted in FIG. 11 as the left ventricular end-diastolic pressure

(LVEDP)) increases. This stretching of the myocytes causes an increase in force generation which enables the heart to eject the additional venous return, thereby increasing the stoke volume (SV). Thus, increasing venous return and ventricular preload leads to an increase in stroke volume as shown in the FIG. 11. Frank Starling curves vary from heart to heart based on various factors, like contractility, wall stress, sphericity index, diseased state etc. The curve that best matches a given patient may be obtained by comparing the patient specific characteristics to those of other patients in a database of other heart models ((14), FIG. 3). FIG. 12 depicts an embodiment of a graph of pressure volume loops during a cardiac cycle.

On page 36, please delete the paragraph beginning on line 7, and substitute therefor:

A hemodynamic model, for example, has been developed and published by Professor Ying Sun, et. al., "A comprehensive model for right-left heart interaction under the influence of pericardium and baroreflex, The Amerimay Journal of Physiology, 1997, pp. H1499-H1514, which is incorporated herein by reference. The hemodynamic and physiological models may interact with the finite element model to show the physician what effect his interaction has had on the other elements and the whole heart. Physiological models may vary from very simple such as an equation of a curve of Stroke Volume vs. End Diastolic Volume as in the Frank-Starling curve (FIG. 11), to much more complicated computational biology models. Hemodynamic models may also vary from simple models of the pressure drop vs. flow relationship to complex computational flow dynamics like the one published by Makhijani et. al. " Three-dimensional coupled fluid - Structure simulation of pericardial bioprosthetic aortic valve function" ASAIO Journal 1997; 43:M387-M392, which is incorporated herein by reference.

On page 36, please delete the paragraph beginning on line 21, and substitute therefor:

In an embodiment, a placement of an annuloplasty ring may be simulated to show its effect on annulus 211, connected tissue 212 and ventricle 210 (see FIG. 14). The patient's heart may be imaged (10). The image may be converted to a finite element model (11). Software may allow the physician to select the type of treatment desired (12). The physician may be able to access a database to select a device to be used (22). In the current embodiment, an annuloplasty ring would be an example of a device selected. The model may display to the physician the mitral valve. The model may allow the physician to instruct the model on where to position the ring. In some embodiments, a model may suggest where to position an annuloplasty ring based on a desired outcome of the procedure. The desired outcome may be indicated by the physician. The model may assess which suture to use in securing the ring. The model may assess how much tension to put on the sutures. The model may assess a distance between each bite etc (13). The model may then apply the intervention to the mitral valve annulus, the other elements of the mitral valve, the other components of the ventricle, and/or the heart as a whole (16). The software may recreate the image on the monitor to show the physician the effects of his interaction (17). The potential clinical outcomes (18) may be assessed through use of the model through interaction with the physiological and hemodynamic models such as the graphs depicted in FIG. 13. In FIG. 13, hemodynamics for left heart failure are on the left and Right heart failure are on the right). P_{lv} - left ventricular pressure, p_{ao} - Aortic pressure, p_{la} - Left atrial pressure, p_{ra} - right atrial pressure, p_{rv} - right ventricular pressure, p_{pa} - pulmonary arterial pressure, p_{ra} - right atrial pressure, q_{vc} - flow through venacava, q_{pa} - flow through aortic valve, v_{lv} - volumen of left ventricle, v_{la} - volume of left atrium, v_{rv} - volume of right ventricle, v_{ra} - Volume of right atrium. In an embodiment, a simulation may show an annuloplasty ring's effect on the size and/or

orientation of the annulus. A simulation may show an effect the ring may have on the connected tissue, e.g., does it affect the length of the chordae tendinae, shape of the ventricle, etc. A model may be analyzed to show the surface area of the opening of the shortened annulus, how much flow may come through that opening, and/or how the change in flow may affect the ventricle. The model may predict if there is a mitral valve prolapse.

On page 37, please delete the paragraph beginning on line 21, and substitute therefor:

In an embodiment, a database of medical devices, for example the device depicted in FIGS. 14-18, may be created and accessed to allow the simulation of these devices. These devices may be tested for physical properties and these physical properties encoded into a finite element model, as has been done for elements of the heart described above. The finite element models for the devices may be stored in the database (22). The devices may be accessed by the physician by selecting the object by its common name. For example, prosthetic valves and/or prosthetic valve apparatus (mechanical and bioprosthetic) may be called upon to place different artificial valves into the heart. The performance of the heart with the different valves may be assessed to select the correct valve for the patient. The model might also give estimated values of post-surgery performance of the heart. The model may display estimated ejection fraction, regurgitation, sphericity of ventricle, volume of the ventricle, percentage of shortening on the long and short axis, and maximum and minimum flows across the valves, and/or tension in chordae etc. In some instances, it is likely that off the shelf devices do not provide optimum results. For example, annuloplasty rings comes in various sizes. It is likely that for a given patient, when a smaller size is used, the annuloplasty ring may end up creating more than acceptable tension in the chordae. Using the next size of the

annuloplasty ring may lead to mitral insufficiency. In a situation where available sizes of the device are insufficient, the model may come up with a specification for the ring that falls between those two sizes. A patient specific designed device may offer the best possible outcome for the patient.

On page 39, please delete the paragraph beginning on line 17, and substitute therefor:

FIG. 17 depicts a model of a mechanical heart valve 232. FIG. 18 depicts one embodiment of a model of an acorn corcap. Acorn corcap 253 may be positioned around ventricle 251 of heart 250 to prevent further dilatation and to reduce wall stress.

On page 40, please delete the paragraph beginning on line 28, and substitute therefor:

In another embodiment, the software method depicted in FIG. 3 may be used to model a surgical procedure. Images of a heart and specifically the ventricle are taken (10) and a finite element mesh model is created of the ventricle and of the features as described previously (11). A user chooses a treatment option (12) (e.g., surgical ventricular repair). The user, using pull down menus or another standard interactive means, chooses the implements that are needed to perform the surgical procedure (12). The physician may perform the treatment by interacting with the image and the model (13). Interacting with the model, the physician may for example select a scalpel. The surgeon may then identify where and/or how to incise the ventricle with the selected scalpel (as depicted in FIG. 19). After a user makes an incision, the user then identifies the tissue he wants to exclude and places a Fontan stitch 182 with suture 181, as depicted in FIG. 20. When the physician excludes tissue the model eliminates the sections of the

finite model that correspond to this area from the calculations of the ventricle parameters and outcomes. A model may keep these elements solely as graphical depictions. A model may try various degrees of volume reduction of the ventricle and/or changes in the shape of the ventricle. A computer system may attempt these types of reconstruction automatically and/or upon a request from a user. The finite element model may calculate this change in shape of the ventricle and calculate how this change has affected the other features of the ventricle and the heart.

On page 41, please delete the paragraph beginning on line 17, and substitute therefor:

FIGS. 19-24 depict embodiments of a sequence of a surgical procedure modeled on a virtual heart. The embodiment depicted is that of a left ventricle reconstruction. In an embodiment, FIG. 19 depicts an embodiment of making an incision from point 151 to 152, thus forming an opening 153 in ventricle 150. FIG. 22 depicts a placement of sutures 161 and 162 and opening up an incision in a ventricle during an actual surgical procedure. FIG. 23 depicts a representation of shaper 173 placed in opening 172 of ventricle 150. FIG. 23 depicts an example of how a ventricle is reconstructed during an actual surgical procedure. FIG. 20 depicts an embodiment of a Fontan Stitch. In one embodiment, during an actual surgical procedure, a surgeon may want to imbricate 193 stretched tissue 192 (as depicted in FIG. 24). During an assessment of a virtual procedure a computer system may instruct a user what features of a heart could be modified to achieve the desired result including using such methods as depicted in FIGS. 19-24.

On page 44, please delete the paragraph beginning on line 8, and substitute therefor:

In some embodiments, distances and angles between papillary muscles and other portions or features of a heart may be assessed using portions of the imaging method described herein. The positions and/or angles of papillary muscles to each other or to a mitral valve of a heart are useful indicators for assessing a condition of a heart. One problem with current imaging technology (e.g., MRI) is that it is difficult to determine the exact point of intersection of one or both papillary muscles. This difficulty arises from the problems of most imaging techniques of obtaining an image of the point of intersection of a beating heart. In an embodiment, a plurality of images (e.g., from an MRI) may be provided to a computer system. At least a two-dimensional image along the y-axis may be extrapolated from the images provided to the computer system (depicted in FIG. 29). In other embodiments an at least a three-dimensional image may be created from the plurality of images. A computer system may assess the position of one or both papillary muscles 602 in heart 600. The computer system may assess a point of intersection 604 between one or both of papillary muscles 602 and an endocardial wall using image enhancement and contrast identification as described herein. A computer system may assess points of intersection by comparing an image created by the computer system to a heart features database. A computer system may also assess one or more angles 606 between one or more of papillary muscles 602 and mitral valve 604. In some embodiments, a user may virtually mark points of intersection on an image created by a computer system. The computers system may then automatically calculate distances and angles from these reference points.

On page 45, please delete the paragraph beginning on line 19, and substitute therefor:

In an embodiment, an optimal solution to reconstruct a ventricle may require the use of a patch to reinforce a septum and/or close a hole remaining in the ventricle. A

model may be able to show the physician what shape patch may be needed to perform the ventricular reconstruction. A specially constructed patch may be made for this patient. A method to manufacture this custom patch could be to purchase cardiovascular patches currently sold by, for example Boston Scientific/Meadox, or W. L. Gore. The model may generate a CAD file defining the shape of the opening in the ventricle. The shape of the opening may be printed and used as a template. The template could be placed on the patch and the patch cut to the shape and then sterilized. FIG. 31 depicts embodiments of various potential patches 361-364 of different sizes and shapes to seal an opening in a ventricle. The model may lead to other tools that help the physician implement the solution that the model has created like a patch with an apex, etc. FIG. 32 depicts an embodiment of a patch that has an apical shape. Apical patch 365 may include tip 366 (e.g., an apex) and base 367. Apical patch 365 may include a concave interior surface that may function as at least a portion of the interior surface of a reconstructed ventricle. Apex 366 may function as the new apex of a reconstructed ventricle.

On page 48, please delete the paragraph beginning on line 1, and substitute therefor:

A set of acceptable physiological and hemodynamic criteria may be entered in a computer model (55). Acceptance criteria include, but are not limited to a stroke volume index, a pulmonary artery pressure, an ejection fractionand/or an end systolic volume index. The acceptance criteria may be entered by the physician, or may be selected by the software base don information collected about the patient.

On page 48, please delete the paragraph beginning on line 19, and substitute therefor:

The computer model may be used to analyze what effects the selected virtual treatment may have on the patient's heart. The insertion of cardiac devices or the performance of a surgical technique may alter the geometry of a patient's heart. The modeling software may alter the model of the patient's heart (58) in response to the selected treatment. Additionally, the computer software may automatically determine the effect of the treatment on various features of the patient's heart (59). For example, the software may calculate physiological properties of the heart based on known properties of hearts. The results of these calculations may be used to create a new model of the patient's heart.

On page 49, please delete the paragraph beginning on line 19, and substitute therefor:

After at least a portion of the automated analysis has been completed, the software may indicate to the physician that treatment options have been determined (70). The physician may access these treatment options and use the displayed information to diagnose the outcome of the proposed treatment on a patients heart (70). Diagnosing the effect of the procedure on a cardiac irregularity, where cardiac irregularities may include, but are not limited to, structural, chemical, and/or electrical irregularities may include comparing the simulated computer model of the outcome of the treatment to what is generally accepted to one skilled in the art as a healthy/normal heart. Cardiac treatments may be assessed/determined by analysis of a model of each procedure (procedure not being limited merely to a surgical procedure). Treatments may also be assessed relative to a database of heart models 61, where the database of heart models may include, but is not limited to, data from prior cardiac surgical procedures and/or treatments, expert opinions (e.g., cardiac surgeon specialists), and/or data derived and/or extrapolated from prior cardiac surgical procedures/treatments and/or expert opinions.

On page 50, please delete the paragraph beginning on line 26, and substitute therefor:

A process for determining the akinetic segments of a patient's heart is depicted in FIG. 34. Before treatment, in order to assess which areas of the heart may need to be repaired or replaced, the patient may undergo an imaging procedure such as an MRI smay, PET smay or an Echocardiography smay to determine the location and condition of the components of the heart. Initially, imaging data is collected of the patient's heart (75). Since the images are captured of the patient's heart while it is beating, the stage of beating that the heart is in is taken into account when creating a model of the heart. In one embodiment, the systolic and the diastolic images of the patient's heart are separated (76). These separated images can then be used to create separate, three-dimensional models of the heart in systole mode and diastole mode (77).

On page 51, please delete the paragraph beginning on line 17, and substitute therefor:

One of the problems surgeons confront while doing an SVR procedure is how to determine the demarcation line between viable and akinetic tissue. For this purpose a non-interactive model, which may show the location of a diseased area of the ventricle (82), may be developed using a method as described in FIG. 34. The model may show on the image which areas of the ventricle are akinetic or dyskinetic to determine which areas might be excluded during an SVR procedure. A variety of different algorithms may be used to identify the akinetic tissue (78). Borders of the akinetic tissue may be identified (79).

On page 52, please delete the paragraph beginning on line 5, and substitute therefor:

In an embodiment, a geometric center of the heart is calculated and imaginary lines (rays) 123 are drawn from this center (see FIG. 37). Two points on each ray are recorded; the points are defined as point of intersection of the ray to the endocardium and epicardial boundary. For instance, X_A 125 and Y_A 124 are points on the border zone in this plane. The distance between these two points gives the wall thickness (d). Wall thickness is calculated on the diastole image d_d and on the systole image d_s. As shown in FIG. 36, the wall thickness at the diastole is $d_d = CL_{DO} - CL_{DI}$. Similarly, the wall thickness at the systole is $d_s = CL_{SO} - CL_{SI}$. Normally $d_s > d_d$ when the heart functions normally, that is because the myocardial wall thickens during systole to create pumping action. If a section of the heart muscle is diseased then $d_s = d_d$, meaning that portion of the wall is not thickening, it is referred to as akinetic tissue, it could either dead or non-contributing tissue. All the rays that correspond to akinetic tissue are identified (all rays where $d_s = d_d$) by analysis of the collected images. The boundary layer of the akinetic area is then established by comparing each of the akinetic rays to its neighboring rays. It is generally accepted that if a wall thickness of a portion of a heart is less than 5 mm, then that portion is effectively akinetic. For any given akinetic ray, if at least one of its neighboring rays is kinetic ($d_s > d_d$) then that akinetic ray is the boundary layer ray. Once all rays on the boundary layer are identified, the point of intersection of the boundary layer rays on the endocardial boundary defines the border zone between the viable and akinetic tissue. In an embodiment, a computer system may create an image of an assessed wall thickness. An image may include progressive coloring to differentiate an extent of wall thinning and/or dead tissue (i.e., when the wall thickness is less than 5 mm).

On page 54, please delete the paragraph beginning on line 26, and substitute therefor:

In an embodiment, once a location of the diseased section is identified with respect to other cardiac structures, a 3D CAD file (DXF or STL files) may be generated which shows the location of the border area with respect to a known landmark on the heart. Referring back to FIG. 34, a template may be created that identifies the location of the akinetic tissue. FIG. 38 depicts an embodiment of mesh structure template 330 that may be generated from a 3D CAD file with border areas 331, 332 indicated on the mesh. Mesh structure 330 may be used to assist a user in locating a diseased portion of an actual heart during a surgical procedure. FIG. 39 depicts an embodiment of an alternate template 350. A pre-cut shape is formed based on the modeling program to assist a user to identify, on a heart, a diseased tissue 351 during an actual surgical procedure. In an embodiment, an at least three-dimensional image may be created demonstrating a diseased section. In addition, a diseased section may include "progressive coloring." Progressive coloring may assist a user in visualizing and understanding at least an extent of the diseased section. Progressive coloring may in general be defined as displaying an extent to which a condition exists by relating a relative extent of the condition to a relative gradient in color. For example, the greater an irregularity of a portion of heart tissue, the greater the contrast in a color of the portion is relative to another portion of heart tissue in an image. Color, it should be pointed out, includes grayscale as well. One may then create a template that may match the diseased area. The template may include anatomical landmarks from the heart such as Left Anterior Descending artery or the Atrial ventricular groove. The anatomical landmarks may ease alignment of the template to the diseased area. The template may be in a form of a balloon that is patient specific with the same shape and/or size as the interior of the ventricle. The template may include a border zone marked on the template. The template may be like a glove that fits on the outside of

the heart with border zone and landmark points marked on it. Such tools may be very helpful in order to execute SVR procedure with greater precision.

On page 57, please delete the paragraph beginning on line 14, and substitute therefor:

In an embodiment, when the tissue is excluded as described herein, there may be a hole left in the ventricle that a surgeon will fill. One device that might cover this hole is a patch that could aid in the contraction of the left ventricle. One form of this patch may be made of a fabric that is pretensioned and stretched to fill the hole left in the ventricle. The pretensioning places stress on the fibers, which assist the ventricle in contraction when going back to their relaxed state during systole. Another variation could be that the short axis fibers are of a different strength than the long axis fibers, thus aiding the greater contraction along the short axis FIG. 42. FIG. 42 depicts an embodiment of a patch 400 with fibers that have strength in one axis different from a strength in another axis. The patch could have the pretensioned fibers only in the center of the patch, decreasing the tension exerted by the patch on the ventricle walls, but still providing some assistance to the ventricle during contraction.

In the Drawings:

The attached sheets (sheets 4, 6, 12-18, and 26 of 28) of drawings include amendments to Figures 4, 6, 17-19, 21-24, 26, 29, and 39. These sheets, which include Figures 4, 6-7, 16-29, and 37-39, replace the original sheets including Figures 4, 6-7, 16-29, and 37-39. In FIG. 4, element 90 has been amended to read 91. In FIG. 6, previously omitted element 91 has been added. In FIG. 17, elements 230-231 and 233-235 have been removed. In FIG. 18, element 252 has been removed. In FIG. 19, an unnumbered heart element located above and previously detached from the figure has been repositioned so as to be coupled to the heart. In FIG. 21, elements 281, 282, and 283 have been amended to read 182, 181, and "Tension" respectively. In FIG. 22, elements 160 and 163 have been amended to read 290 and "Tension" respectively. In FIG. 23, elements 170 and 171 have been amended to read 290 and 181 respectively. In FIG. 24, element 191 has been amended to read 181 and elements 190 and 194 have been removed. In FIG. 26, element 270 has been amended to read 290. In FIG. 29, previously omitted element 608 has been added and element 604 has been removed. In FIG. 39, element 352 have been removed.